

IMPROVED TAMPER EVIDENT END CAP ASSEMBLY  
FOR A LOADED SYRINGE AND PROCESS

1 BACKGROUND OF THE INVENTION

2 Claim of Priority

3 This is a continuation patent application of a previously  
4 filed and currently pending application, namely, that having  
5 Serial No. 09/853,261 filed on May 11, 2001, which is set to  
6 issue as U.S. Patent No. 6,585,691 on July 1, 2003, the full  
7 content of which is incorporated herein in its entirety by  
8 reference.

9  
10 Field of the Invention

11 This invention relates to an improved tamper evident end  
12 cap assembly for a drug loaded syringe to seal it and to cap it  
13 protectively prior to injecting a patient with the drug; and  
14 also, to the end cap assembly and a package, as a combination,  
15 wherein the end cap assembly is encapsulated within the package  
16 to maintain it in a sterile condition prior to capping a drug  
17 loaded syringe with it; and further, it relates to a drug loaded  
18 syringe capped with the tamper evident end cap assembly ready to  
19 be opened to inject a patient with the drug or to return the  
20 drug load, if not used by the patient, to be down loaded at a  
21 station and recycled. The invention also relates to a process  
22 of manufacturing the end cap assembly and of using it by  
23 installing it on a mating syringe.

1        DESCRIPTION OF THE RELATED ART

2                This invention is disclosed in three forms:

3                a first form, which is a combination, composed of a drug  
4        loaded syringe having a nozzle with a discharge port or luer  
5        opening and a tamper evident end cap assembly according to the  
6        invention installed on the nozzle sealing and closing the luer  
7        opening and which cannot be removed to gain access to the drug  
8        load without creating palpable evidence of tampering;

9                a second form, which is another combination composed of a)  
10       at least one tamper evident end cap assembly which has a  
11       structure according to the invention, and b) a sterile shipping  
12       and storage package encapsulating it, the end cap assembly  
13       including its end cap assembly luer lock syringe cap captivated  
14       within the end cap assembly is adapted to be removed from the  
15       package and installed on the nozzle of a mated standard syringe  
16       in a position from which it cannot be removed without creating  
17       evidence of the removal, and

18               a third form which is an improved combination, composed of  
19       a) a tamper evident end cap assembly which includes b) a luer  
20       lock syringe cap coaxially captivated yet rotatable on its axis  
21       within the assembly, the assembly being for mounting of it over  
22       the discharge port or luer opening of a dose loaded standard and  
23       mated syringe, the end cap assembly being improved with respect  
24       to known devices by structure set forth fully in this disclosure  
25       which, among other elements, includes a) a first one way drive  
26       means component on the syringe cap, b) a floor portion in the

1 assembly to maintain the cap within the assembly which floor  
2 portion also has an axial one way drive means component, which  
3 mates with the first component to comprise a one way drive means  
4 to move the syringe cap axially in one direction only to tighten  
5 it on a syringe nozzle, and is disengaged and inefficient upon  
6 rotation in the other direction of rotation and c) a centering  
7 means on the floor portion to guide the syringe cap of the end  
8 cap assembly into coaxial engaged relation with other end cap  
9 assembly parts.

10 The invention is also of a process of manufacture of the  
11 foregoing structure and of the use of it.

12 Throughout this specification, the phrase "standard  
13 syringe" is used. This phrase is intended to refer to a  
14 plurality of "carbon copy" syringes, usually made by a single  
15 manufacturer. A "carbon copy" syringe is one of a group of  
16 syringes of the same type, as regards size, shape and  
17 configuration which are intended to be used at a particular  
18 medical facility or location. By way of explanation, as is well  
19 known in the field, many facilities use standard syringes made  
20 and sold by a particular manufacturer, such as those of the  
21 Becton Dickenson Company. However, there are syringes of many  
22 other manufacturers which are also in use at many facilities and  
23 these are also referred to herein as standard syringes. The  
24 point is that the subject invention is sized and shaped to mate  
25 with all of the "carbon copies" of a standard luer lock type  
26 syringe stocked for use at a given facility, regardless of the

1 manufacture of the standard syringes used at that particular  
2 facility.

3 As further background generally, and as indicated in Figure  
4 1, a standard luer lock type syringe 11 is usually of plastic  
5 material; and it typically includes a barrel 1 with a nozzle 2,  
6 which are usually transparent or translucent, and define an  
7 elongate interior chamber which is in fluid communication with  
8 an axial luer, passageway or long channel 3 in the syringe  
9 nozzle 2 and that terminates distally at an opening or discharge  
10 port 4; and b) an axially slidable piston 5 in the barrel with  
11 a head 6 provided with a circumferential gasket means 7. When  
12 assembled, the end face 9 of the head 6 of the piston confronts  
13 channel 3 and closes the opening or discharge port 4 of the  
14 syringe. The piston also includes a push rod 8 extending  
15 proximally from the head 6 and from barrel 1 for axially  
16 manipulating the head end face 9, and consequently, the axial  
17 location of the piston head 6 in the barrel 1, either closer to  
18 or withdrawn from, the luer opening or discharge port 4. In  
19 use, the standard syringe 11, after being loaded with a drug at  
20 the pharmacy, is sealed by closing the discharge port 4 with a  
21 mating member often referred to as a luer lock or syringe cap 14  
22 as shown in Figure 2. To do this the cap 14 may be provided  
23 with threads 3" to be threadably connected to the nozzle by a  
24 suitable mating connection means 3'. As shown in Figures 1 and  
25 2, the threads 3" are located on the interior of the nozzle 2 so  
26 as to connect to an exterior of connection means 3'. The

1 connection means of the luer lock or syringe cap 14 may,  
2 alternatively, be of the type which includes the male radially  
3 extending flange portion also indicated as 3' in Figure 2. The  
4 connection may also be of the type which includes a set of  
5 circumferentially spaced ears (not shown) on the outer surface  
6 of the luer lock cap provided to threadably engage the threads  
7 on the syringe. As shown, generally, in Figure 2 in either  
8 case, the ear type or the flange type, the radially extending  
9 portion 3' of the cap 14 is sized and configured for threaded  
10 receipt in the annular, correspondingly threaded recess 3" of  
11 the nozzle 2. In another form, the connection means may be  
12 merely reversed and comprise a female connection means portion  
13 on the luer lock or syringe cap for threaded connection with a  
14 male connection means portion on the nozzle 2. In some  
15 structures, the nozzle portion 2 and syringe cap 14 may each  
16 have a correspondingly tapered mating configuration for press  
17 fitting them together to join them. In this specification the  
18 term, "connection means" refers to and embraces the structure  
19 shown and or described as well as other known and usually  
20 routine means of installing a syringe cap 14 and a mated syringe  
21 11 to close the discharge or dispensing port 4 of the syringe  
22 11.

23 Turning now to the background purposes of the invention, in  
24 a hospital, for example, it is common for medical doctors to  
25 order that a patient be given an oral or an injectable dose of  
26 a drug. In the case of an injectable drug, the dose is quite

1 often filled by a pharmacist at a location which may be regarded  
2 as a syringe filling station. It is often far from the place  
3 where the patient is to be injected. It is quite often that a  
4 syringe filling station is located on one floor of a hospital  
5 and the nurse's station is located on another hospital floor.  
6 Indeed, at large medical facilities, a syringe filling station  
7 may resemble a factory on the hospital grounds from which drug  
8 loaded syringes are delivered to multiple nurse stations in  
9 multiple other hospital buildings. Because of the remote  
10 location of many nurse's stations relative to an associated  
11 syringe filling station, a loaded syringe is very often given to  
12 another person for delivery to a nurse's station for subsequent  
13 dosing of the patient by a duly qualified nurse or other  
14 medically trained person.

15 During the process of loading the syringe with a drug dose,  
16 the delivery of the dosed syringe and its handling in general  
17 prior to the step of actually dosing a patient by injection,  
18 there is a danger of contamination. This invention guards  
19 against that happening.

20 Also, especially in the case of a very expensive drug or an  
21 addictive dose, there is a danger of tampering with the loaded  
22 syringe in an effort to improperly gain premature access to the  
23 drug. A real danger is that such inappropriate action may  
24 result in a substitution of an unauthorized material in the  
25 syringe, simulating an actual prescribed or real dose.  
26 Obviously, a substitution of a substitute dose for a real dose,

1 such as a substitution of a saline solution for a dose of  
2 morphine, may have extremely serious consequences. Thus, there  
3 is a problem of knowing if a sealed drug laden syringe has, or  
4 has not, been exposed to contamination or compromised by  
5 tampering. This and other problems have been further described  
6 in my earlier granted U. S. Patent No. 4,667,837 and in other  
7 patents including in Patent No. 5, 328,474.

8 This invention addresses problems of making and using drug  
9 loaded syringes, some of which are described in each of the  
10 above noted patents. This is because problems remain in the  
11 field since the introduction of products according to those two  
12 patents. These include problems of easy and inexpensive  
13 assembly of the end cap assemblies in the manufacture of them,  
14 problems involved in the assembly of an end cap assembly on a  
15 drug loaded syringe at a drug filling station, and problems of  
16 maintaining sterility during storage at the manufacturing  
17 facility of the end cap assemblies, transport of them to a  
18 medical or other facility storage, and problems of storage of  
19 them at a medical facility. In summary, the invention addresses  
20 problems in handling the end cap assemblies as one is made and  
21 used at different stations by different persons. In general,  
22 this invention provides an improved tamper evident end cap  
23 assembly being less expensive, safe and structured for  
24 convenient manufacture and use.

25 Specifically, this invention addresses outstanding problems  
26 by providing: a) an improved tamper evident end cap assembly

1 including a captivated luer lock syringe cap for closing the  
2 discharge port in the nozzle of a loaded syringe, b) an  
3 improved sterile package with the end cap assembly encapsulated  
4 within it, for transport to, and, prior to use, for storage at  
5 a medical facility; and c) an improved combination of a drug  
6 loaded syringe and tamper evident end cap assembly for use in  
7 dosing a patient. The end cap assembly is especially adapted to  
8 mate with and be used with what is referred to herein as a  
9 standard syringe, one which is a "carbon copy" of the type used  
10 at a given medical facility where it is drug loaded and  
11 delivered to a nurse's station for injecting a patient with the  
12 dose. Any unauthorized access to the loaded drug contents,  
13 once the syringe has been loaded and closed prior to its  
14 ultimate use, requires removal of the syringe cap by an  
15 unauthorized person, and the fact that such a removal occurred  
16 is clearly evident, if it does in fact happen.

#### 18 SUMMARY OF THE INVENTION

19 Generally, in a first form, this invention provides an  
20 improved tamper evident end cap assembly including a captivated  
21 luer lock syringe cap for closing the discharge port on the  
22 nozzle of a drug loaded syringe. In another form, the invention  
23 provides a combination composed of a) the improved end cap  
24 assembly and b) a sterile package to keep the end cap, or a  
25 plurality of such end cap assemblies, sterile during a period of  
26 storage at a manufacturing site, during transport of it to a



1 medical facility, and during storage there until ready for use  
2 capping a drug loaded syringe. In yet another form, the  
3 invention is of an improved tamper evident end cap assembly  
4 mounted on a drug loaded syringe for the "last mile" delivery to  
5 a nurses's station ready for use by dosing a patient by  
6 injection.

7 One specific persistent and troubling problem that has  
8 remained in the field is overcome by the disclosed structure.  
9 That problem is caused by the fact that many syringes and doses  
10 are of very low volume. With earlier tamper evident syringes a  
11 problem has been that, inadvertently, a small loaded syringe can  
12 pass axially through an end cap assembly during the step of  
13 capping a drug loaded syringe. This is especially true in the  
14 case of syringes sized for a one cubic centimeter charge of a  
15 drug. The improved structure of this invention resolves this  
16 problem. It provides a blocking means so this cannot happen.

17 Another problem is that syringe drug doses are often  
18 wasted. In medical practice a doctor often writes orders  
19 directing that "up to" a certain amount of a drug, a limit which  
20 can be safely tolerated by a patient, may be administered, if  
21 requested by the patient or circumstances justify it. This  
22 often results in drug doses being loaded into many syringes  
23 which doses are not actually administered. These drug doses  
24 can be routinely recycled provided if there is an assurance that  
25 the drug has not been contaminated and the syringe can be opened  
26 without comprising the drug. This invention provides structure

1 which accommodates that purpose.

2 After being filled with a drug at a syringe filling  
3 station, the loaded syringe is delivered to an injection  
4 location for dosing a patient. Especially while being  
5 delivered, accidental contamination is substantially prevented  
6 by this invention and importantly, any unauthorized tampering in  
7 an effort to access a drug in a loaded syringe with an end cap  
8 assembly according to this invention is clearly evident. Also,  
9 whatever the specifications are of a manufacturer for his  
10 particular syringe, which is standard at a given facility, the  
11 invention is adapted to be "tailor made" or sized to accommodate  
12 that standard syringe of that facility.

#### 13 14 OBJECTS OF THE INVENTION

15 It is an overall object of this invention to provide an  
16 improved tamper evident end cap assembly which includes a  
17 captivated lure lock syringe cap for closing the discharge port  
18 or, luer opening, in the nozzle of a loaded syringe.

19 It is also an object to provide a sterile combination  
20 composed of: a) one or more tamper evident end cap assemblies  
21 according to this invention which includes a mating luer lock  
22 syringe cap captivated in the assembly; and b) a sterile  
23 shipping and storage package encapsulating the assembly.

24 It is a further object to provide a captivated luer lock  
25 syringe cap which includes a) a first one way drive means  
26 component on the luer lock or syringe cap to mate with a

1 companionate second one way drive means component on another  
2 part of the end cap assembly, which is a mirror image of the  
3 first component, and, when the components are engaged comprise  
4 a drive means to install the cap on a syringe, and,  
5 additionally, b) a means to center the lure lock syringe cap so  
6 that it is rotatable within the end cap assembly and also is in  
7 coaxial relation and engaged with the other end cap assembly  
8 parts for driving advancement of the end cap assembly in a  
9 single axial direction along a syringe nozzle upon relative  
10 rotation of the end cap. This one way drive mechanism in the  
11 described preferred embodiment comprises what may be referred to  
12 aptly, and be conveniently denominated as, screw or rotational  
13 type "ramp and cliff assemblies". It is one which is capable of  
14 axially moving a moveable member a predetermined axial distance  
15 in one direction only. This, in turn, determines the force  
16 required to move the cap member not by rotating the assembly but  
17 by applying the force axially to withdraw it and gain access to  
18 a drug load in a syringe. This invention provides structure for  
19 a predetermined tightness of the cap once installed on the  
20 nozzle of a mating syringe. Thus, the invention facilitates  
21 recycling of unused drugs. This one way drive mechanism is  
22 referred to and described where appropriate as "ramp and cliff  
23 assemblies" in this specification although other equivalent  
24 structure may be provided to achieve the same result in the same  
25 way within the spirit of the invention as is well known in this  
26 art.

1           An overall object is to provide an end cap assembly which,  
2           once installed on a syringe, will reveal if an axial force has  
3           been applied to separate it from the syringe that is greater  
4           than occurs in normal transport and handling and is great enough  
5           to break the sealed condition of a drug loaded in the syringe  
6           possibly compromising it so that it cannot be recycled with  
7           assurances of safety.

8           It is a general object to disclose the forms of the  
9           invention in a best mode and in preferred embodiments; and  
10          accordingly this disclosure is addressed to those in the art in  
11          sufficient detail to make and use the invention, which may be  
12          transported and stored in a sterile condition, is composed of  
13          readily available materials and structure which is easy to use,  
14          and is otherwise well adapted for the purposes expressly and  
15          implicitly indicated herein.

16          It is also an object of the invention to provide a process  
17          of making the invention in its various forms and of using it.

18          In accordance with these and other objects which will be  
19          apparent to those in the field, the subject invention is  
20          described in the following paragraphs on reference to the  
21          accompanying drawings illustrating the invention in a preferred  
22          embodiment which is not intended to be limiting.

#### 23 24          BRIEF DESCRIPTION OF THE DRAWINGS

25          Figure 1 is a general pictorial view representing one of  
26          many known standard syringes and which is representative of one

1 on which the end cap assembly invention is to be installed for  
2 use in capping it after a drug has been loaded into it.

3 Figure 2 is a side view, in partial cutaway and section of  
4 a syringe cap, generally having a male thread, or either an end  
5 flange, as shown, or a set of circumferentially spaced ears,  
6 and when assembled is captivated as a part within the subject  
7 end cap assembly.

8 Figure 3 is a pictorial view illustrating only a part of  
9 the cap assembly, namely, a cup shaped end cap member.

10 Figure 4 is a side view in cross section of the end cap  
11 member seen in Figure 3.

12 Figure 5 is a view in cross section of the end cap member  
13 seen in Figures 3 and 4 taken along line 5-5.

14 Figure 6 is a detail view in partial cutaway of the end cap  
15 member shown in Figure 5.

16 Figure 7 is a cross sectional view along line 7-7 of Figure  
17 6.

18 Figure 8 is a side view of an end wall or floor piece which  
19 closes one end of the end cap member of Figures 3, 4 and 5.

20 Figure 9 is an end view of Figure 8 illustrating the  
21 configuration of the one way drive component and the centering  
22 means of this element.

23 Figure 10 is an enlarged detail view of the end wall or  
24 floor piece of Figure 8.

25 Figure 11 is a cross sectional view of the end cap assembly  
26 of the subject invention including the syringe cap seen in

1 Figure 2, the end cap member seen in Figures 3, 4 and 5, and the  
2 end wall member or floor piece seen in Figures 8 and 9.

3 Figure 12 is an exploded view illustrating the relative  
4 arrangement of the elements prior to assembling the end cap  
5 assembly seen in Figure 11.

6 Figure 13 is an enlarged exploded view illustrating the  
7 relative arrangement of the syringe, the end cap assembly parts,  
8 and the sterile package for the end cap parts after it is  
9 assembled, it being noted that the actual syringe cap is  
10 captivated within the end cap assembly when it is removed from  
11 the sterile package for a final assembly on a drug loaded  
12 syringe to sealingly close it.

13 Figure 14 is a side view in partial section and cutaway of  
14 the embodiment of Figure 11 in assembled form.

#### 15 16 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

17 Generally, Figure 11 discloses the present invention in at  
18 least a partially assembled form 17. It is a tamper evident cap  
19 assembly 10 for a drug loaded syringe. The cap assembly 10  
20 includes a specially shaped and captivated syringe cap 14 within  
21 it. In use, the syringe cap 14, is applied over the discharge  
22 port 4 on the end cannula 2' of the nozzle 2 of a conventional  
23 syringe 11, of the type shown in Figure 1, after it has been  
24 loaded with a drug. This closes and seals, or caps, the opening  
25 or discharge port 4 of a lumen 3 which is formed within cannula  
26 2' and is in fluid communication with the drug in the syringe

1 barrel 1. A supply of end cap assemblies 10 each in an  
2 individual package 12 may be kept at a drug dispensing location,  
3 although a package may contain multiple end caps assemblies 10  
4 if desired. Prior to use, each of the end cap assemblies 10 is  
5 in a sterile condition having been packaged, transported to, and  
6 stored at the drug dispensing location in a sterile packaged  
7 form for use, upon removal of it from the package, in capping a  
8 drug loaded syringe.

9 Accordingly, the invention in its basic form is an improved  
10 tamper evident syringe cap assembly 10. Also, a form of the  
11 invention is the combination of the tamper evident end cap  
12 assembly 10, including the captivated luer lock cap within it,  
13 and a drug loaded standard syringe 11. When the end cap  
14 assembly 10 is installed on a mated drug loaded standard syringe  
15 11, the end cap assembly 10 and syringe 11 cannot be  
16 disassembled in a tampering effort to "get at" the loaded drug  
17 without causing the end cap assembly 10 to break into pieces  
18 leaving "tell tale" evidence of the tampering. As will be  
19 discussed in greater detail hereinafter, at least one of the  
20 pieces is in the form of a tampering indicator member or  
21 indicator ring 20 that floats free on the syringe nozzle 2,  
22 after tampering.

23 Further, prior to assembly of the tamper evident end cap  
24 assembly 10 with a drug loaded syringe, the end cap assembly 10,  
25 while in an individual package 12, as it is generally disclosed  
26 herein, constitutes an end cap assembly and package combination

1 disclosed in an unassembled relation in Figure 12. When  
2 individually contained within package 12, the combination of  
3 Figures 11 and 12 is adapted for a) sterilization as a  
4 manufacturing step, b) storage with a substantial shelf life in  
5 a warehouse, c) shipment on demand to a drug dispensing  
6 facility, d) a second storage period at the facility, and e)  
7 subsequent use at the medical facility. By reason of the  
8 disclosed sterile structure of the combination 17, composed of  
9 the end cap assembly 10 and its package 12, the package 12 may  
10 be readily opened and the end cap assembly combination 17 of  
11 Figure 11 removed from it and installed on a drug loaded syringe  
12 11 for delivery to a patient to be ultimately used for dosing a  
13 patient. In fact, the package 12 may be utilized to grip the  
14 end cap assembly 10 while it is being installed so that the  
15 sterile condition of the end cap assembly 10 is not compromised  
16 by "hands on" manipulation of it. As shown in Figures 12 and  
17 13, the package 12 may comprise a shell like body 12A disposable  
18 in surrounding and enclosing relation to the assembled end cap  
19 assembly combination 17 as disclosed in Figure 11. A radially  
20 extending peripheral flange 12B may also be provided for  
21 purposes of handling and/or separation of the package 12 from  
22 the combined end cap assembly 10, as indicated as 17 in Figure  
23 11.



## Structure of the Syringe Cap

Lure lock caps and like structures for syringe nozzles are not new in the art. The structure of a syringe cap 14 of this invention is, however, different from known structures and is described conveniently with reference to Figure 2. It includes a body 40 having a) a first axially extending portion 42 of a relatively small diameter with an end face 44 and a blind axially extending channel 46 with a closed inner end 46', and b) a second oppositely extending portion 48 of a larger diameter than that of the first portion 42 which has an opposite end face 50 and which also has a blind or closed axial recess 51 extending toward, but not to, the channel 46. The channel 46 receives nozzle 2, wherein end 46' restricts fluid from exiting discharge port 4. An annular skirt 52 defines an axially facing septum surface 54 within the skirt. On the first axially extending portion 42, a connection means 3' in the form of an annular flange, is provided for threaded attachment on a standard syringe nozzle portion 2 equipped with a mating thread means 3" to open or to close the syringe discharge port 4, as is conventional. Alternatively, lugs or a set of circumferentially spaced ears may be provided to threadably engage a companionate thread means portion in a skirt on the discharge end of a syringe nozzle portion 2. The interior septum surface 54 of the syringe end cap 14, located within the skirt 52 is formed with a pattern in relief. The pattern results in a pair of diametrically spaced ramp and cliff means, comprising a first

1 one way drive structure 58 disposed and structured to engage a  
2 mating surface constituting a second drive structure 58' formed  
3 the floor piece 18 as shown in Figures 8 and 9, which is  
4 described hereinafter. Medical grade materials for the luer cap  
5 are well known, conventionally used in the art, readily  
6 available, and suitable for the luer lock syringe cap 14 as well  
7 as the other parts of the invention.

#### 8 9 General Overview of the Structure of Tamper Evident Cap Assembly

10 The tamper evident end cap assembly 10 is composed of two  
11 chief structural elements: a generally cup or sleeve shaped end  
12 cap member 13 which forms a shield, and the syringe cap 14  
13 loosely captivated within the end cap member 13. Importantly,  
14 the end cap member 13 further includes an end wall piece or  
15 floor piece 18 comprising means to captivate the syringe cap 14  
16 within the end cap member 13, constraining it such that  
17 generally only a rotational and limited axial movement occurs  
18 between the septum surface 54 and the end wall or floor piece  
19 18. Simply put, the syringe cap 14 is free to rotate in the  
20 end cap member 13 but it is captivated loosely, as opposed to  
21 tightly within the end cap member 13; and it is constrained to  
22 only limited axial movement of a predetermined distance in one  
23 axial direction only. To this purpose, the inner end face of  
24 the floor piece 18 is configured to form a pattern in relief  
25 comprising the aforementioned second, one way drive structure  
26 58', which is sized and configured to mate with the first

1 mentioned pattern in relief comprising the first drive structure  
2 58 and which is a mirror image of the pattern in relief of the  
3 first drive structure 58 formed on the septum face 54 in the  
4 syringe cap 14. These components engage one another upon  
5 assembly and comprise a one way drive assembly 58 and 58' for  
6 installing the combined assembly 17 of Figure 11 on a syringe  
7 nozzle 2. In other words the floor piece 18, specifically its  
8 inner end surface when disposed in the cup shaped member 13, and  
9 the captivated syringe cap 14, specifically its septum surface  
10 54 within the skirt 52, confront one another, engage and  
11 comprise a one way drive assembly 58 and 58' to axially displace  
12 the syringe a predetermined axial distance on relative rotation  
13 of these two pieces for installing of the end cap assembly 10,  
14 as a whole, on a drug loaded syringe. This one way drive  
15 assembly to engage and drive the confronting first and second  
16 drive structures 58 and 58' are seen best indicated in the  
17 assembled combination 17 including the end cap assembly 10 of  
18 Figure 11.

19  
20 Structure of the Cup Shaped End Cap Member or Sleeve Form Shield  
21 Element

22  
23 The end cap member 13 is best seen in Figures 3 through 5.  
24 It comprises: a) an outer tubular sleeve 16; b) a cup floor  
25 piece 18 or end wall (see Figures 8 and 9); c) an inner tubular  
26 sleeve 20 or indicator ring; and c) a connecting assembly

1 including one or more frangible tabs or chads 22, normally  
2 connecting the outer sleeve 16 and indicator ring 20 together in  
3 co-axial relation. In at least one preferred embodiment, a  
4 centering means 24 on surface 57' of the floor piece 18,  
5 together with the recess 34, serves the purpose of centering the  
6 floor piece 18 on the end cap member 13. The centering means 24  
7 may comprise an outwardly extending rib or rib segment disposed  
8 to be received within one or more correspondingly dimensioned  
9 grooves or recesses 34 formed in end face 28 of end cap member  
10 13, as best shown in Figures 10 and 4 respectively.

11 Referring to the floor piece 18, as disclosed in Figures 8  
12 - 10 and 12, it is of the preferred shape and size relative to  
13 the end cap 13 as shown. It is seen that it is of a generally  
14 circular plate configuration and has a first or outer main  
15 axially facing surface 51 and a second or inner main axially  
16 facing surface 53. The inner or second main face 53 is echelon  
17 in shape as seen from the side; and the outside surface 51 may  
18 be flat or, as shown, axially recessed, as represented in Figure  
19 8. This forms an outer support surface 55. A central raised  
20 circular surface 57 extends into the cup shaped end cap member  
21 13, an outermost circular surface 57' engages the end face 28 of  
22 end cap 13, and a circular surface 59 of a radial dimension  
23 adequate to loosely engage the open end face of the syringe cap  
24 14 inside the skirt 52 permitting non-binding rotation of the  
25 floor piece 18 and the cup shaped end cap member 13 relative to  
26 the syringe cap 14. The distal tip of the raised circular

1 surface 59 is preferably cone shaped to provide centering action  
2 to guide seating of the syringe cap 14 within the cup shaped end  
3 cap member 13 during manufacture of the end cap assembly 10.  
4 The surface 53 is also configured to form diametrically spaced  
5 ramp and cliff means defining the second drive structure 58' to  
6 cooperate with a pair of diametrical ramp and cliff means  
7 defining the first drive structure 58 on the syringe cap 14.  
8 These constitute, when engaged and mated the aforementioned one  
9 way drive assembly to advance the syringe cap 14 when being  
10 installed on a syringe 11. In a sense the end wall or floor  
11 piece 18 constitutes a tool or means to position and to secure  
12 the syringe cap 14 to a correct degree of tightness on the  
13 syringe nozzle 2 at a predetermined axial location on the nozzle  
14 2 of a mating standard syringe 11. The floor piece 18 also  
15 comprises a generally disk shaped blocking means to keep the  
16 syringe cap in assembly so it cannot fall out. It also is of  
17 sufficient structure to support the end cap 13 when assembled  
18 with the syringe cap 14 within in it. In a preferred embodiment  
19 not shown the entire outer surface 51 of the floor piece 18 may  
20 be flat rather than recessed as shown.

21 The end cap member 13 has a bore or space 26 of a first  
22 predetermined diameter defining an open axially facing mouth 28  
23 and, axially spaced therefrom, an opposite annular axially  
24 facing surface 32. In a preferred embodiment, the axial length  
25 is 0.805 inch; the outside diameter is 0.680; the inside  
26 diameter is 0.488. The indicator member 20 preferably has a

1 ring shape and is coaxially located within the receptacle or  
2 bore 26; and it has an outer cylindrical surface 36 and opposite  
3 annular axial first and second faces, 38 and 40. It is of an  
4 axial length of 0.250; also it is of an outside diameter of  
5 0.488 and an inside diameter of 0.385; and its first axial face  
6 38 is recessed 0.490 from the axially facing mouth 28.

7 A breakable connecting assembly disposed between the outer  
8 sleeve 16 of end cap member 13 and the inwardly disposed  
9 indicator ring 20 comprises a plurality of circumferentially  
10 spaced, frangible lugs, chads or tabs 22. More specifically  
11 from the out side ring surface 36 at preferably equally spaced  
12 locations of two, three or more, the lugs 22, extend radially  
13 outward. The lugs 22 connect the indicator ring 20 to the outer  
14 sleeve 16 maintaining it in the illustrated recessed location in  
15 the outer sleeve 16. The lugs 22 are of a preferably of a  
16 common maximum cross section of 0.045 in a circumferential  
17 measurement and have a semicircular cross section, as best shown  
18 in Figure 7, of a radius of curvature of less dimension than its  
19 circumferential dimension so that the lugs 22 are weakened and  
20 are easily breakable in response to axial forces tending to  
21 separate the indicator ring 20 from the outer sleeve 16 of the  
22 end cap member 13. The end cap member 13 as described, absent  
23 the end wall or floor piece 18 , as will be appreciated by those  
24 skilled in the art, may be of a one piece molded material, as is  
25 the floor piece 18.

## 1 Assembly of the End Cap and Captivated Syringe Cap

2 With the end wall or floor piece 18 not assembled to close  
3 the end opening 28 in the outer sleeve 16, the syringe cap 14 is  
4 moved axially into the outer sleeve 16 with the reduced diameter  
5 portion 42 being received within the inner sleeve or indicator  
6 ring 20 and advanced until the shoulder 42' of the syringe cap  
7 14 abuts the end 38 of the indicator ring 20. As such, the  
8 syringe cap 14 is loosely positioned within the end cap 13. The  
9 end wall or floor 18 is fixedly connected to the end cap member  
10 13 as shown in Figure 11 by suitable well known means, such as  
11 by ultrasonic welding, closing the open end 28 and trapping the  
12 syringe cap 14 and captivating it loosely. This assembled  
13 combination 17 of Figure 11 is thus made ready for gassing after  
14 positioning it in a closed package to sterilize it.

## 16 Assembly of the End Cap Assembly on a Loaded Syringe Nozzle

17 At a pharmacy station of a facility, a standard syringe 11  
18 for that particular facility is loaded with a drug. Thereafter,  
19 the end cap assembly 10 is removed from the package 12 which is  
20 of plyable material preferably in the case of an individually  
21 packaged end cap assembly; and it is then advanced onto the  
22 syringe nozzle 2 by threadably advancing the syringe cap 14 into  
23 a tightened position on the syringe nozzle 2 at a predetermined  
24 axial distance from the drug discharge port 4, closing it and  
25 enshrouding the adjacent surface of the nozzle 2. It is to be  
26 noted that this may be done without comprising the sterility of

1 the end cap assembly 10. The end cap member 13 serves as a tool  
2 for advancing the syringe cap 14 upon tightening rotation of it  
3 through the one way drive comprising the mating formed surfaces  
4 58 and 58' of the syringe cap 14 and the end cap floor piece 18  
5 respectfully. This does not require touching the nozzle 2 or  
6 the syringe cap 14. Upon an attempt to reverse the direction of  
7 rotation of the end cap member 13 from the nozzle 2, the first  
8 and second drive structures 58 and 58' respectively, disconnect  
9 from one another, allowing relative movement between the floor  
10 piece 18 and the syringe cap 14. Therefore, rotation of the end  
11 cap member 13 in the "wrong" direction cannot be used to remove  
12 the tamper proof end cap 13 from the syringe nozzle 2.  
13 Thereafter, access is impossible to the drug in the syringe with  
14 the exception of an outward axial force being applied to the end  
15 cap member 13 of sufficient magnitude to break the indicator  
16 ring 20 free from the outer end cap sleeve 16. This, of course  
17 is only done by one authorized to dose a patient or to recycle  
18 an unused drug charge. However, if done by an unauthorized  
19 person, such as a delivery person while making rounds delivering  
20 the loaded syringe to a nurse station, the tampering would be  
21 immediately apparent because the indicator ring 20 would either  
22 be gone or loosely trapped on the syringe nozzle 2 between the  
23 syringe barrel 1 and syringe cap 14. In short, if tampering  
24 were to take place, the fact that the indicator ring 20 had  
25 been broken free from the outer sleeve 16 would be indicated  
26 either by its absence or it being loosely trapped on the syringe



1 nozzle 2 between the shoulder at the juncture of the syringe  
2 barrel 1 and the nozzle 2. If , then, the syringe cap 14 were  
3 to be threadably withdrawn to gain access to the drug and  
4 something else substituted for it in an effort to disguise what  
5 had happened, this also would be evident because the end cap  
6 member 13 on the syringe 11 would be loose and wobble on the  
7 syringe cap 14. In summary if an unauthorized action of  
8 tampering were to take place or an unauthorized removal of the  
9 luer lock syringe cap 14 were to occur, it would alert others to  
10 that having happened.

#### 11 12 The Sterile Package Including an End Cap Assembly

13 The end cap assembly 10 may be color coded, for example red  
14 may indicate morphine and a different color might indicate a  
15 different drug. An end cap assembly 10 according to the  
16 invention may be packaged in a non porous plastic tray or  
17 blister pack with an out turned open lip surface formed about an  
18 open mouth, which is spanned by a lid composed of sheet material  
19 which is peelable. The material of the lid is preferably Tyvek,  
20 a sterile packaging of spunbonded olefin manufactured from very  
21 fine filaments of high-density polyethylene bonded together by  
22 heat and pressure. Tyvek is the trademark of the material; and  
23 it is made by the E. I. DuPont Company of Wilmington, Delaware  
24 or one of its subsidiaries. It permits sterilization by a gas  
25 under pressure and release of the gas; but it prohibits passage  
26 of micro organisms into the package and therefore maintains the

1 end cap assembly in the tray in a sterile condition prior to  
2 use. An individual assembly is preferred in each tray or  
3 blister with a separate lid associated with each tray or pack.  
4 This is because the sterility of all of a plurality of end cap  
5 assemblies in the same tray or package may become contaminated  
6 and compromised when the a tray lid is removed exposing all  
7 within the tray to ambient conditions. In a preferred  
8 embodiment the assemblies may be in a row of trays joined  
9 together in a strip with cross perforations so that individual  
10 packets may be severed from the strip. Preferably the lids are  
11 provided with a tab to initiate peeling to expose an assembly,  
12 especially when only one of a particular color code is required  
13 at a time.

14 In general it will be appreciated that the dimensions of  
15 the standard syringe will dictate important dimensions of the  
16 luer lock syringe cap 14. For example, the diameter dimension  
17 of the recess in the luer lock syringe cap 14, which, in  
18 assembly, receives the distal end or nozzle 2 of the syringe 11,  
19 and the dimensions of the mating thread means on the outside  
20 diameter as at 3' of the luer lock syringe cap 14, are dictated  
21 by the dimensions of the particular standard syringe 11 which is  
22 outfitted with the invention. Similarly the outside diameter of  
23 the enlarged portion 48 of the luer lock syringe cap 14 will  
24 establish the permissible range of the diameter of the interior  
25 sleeve or indicator ring 20; and so forth, with regard to the  
26 dimensions of each of the elements of the end cap assembly 10.

1 Hence, the actual dimensions set forth herein constitute no  
2 significant part of the invention in and of themselves and,  
3 rather, it is the relative dimensions of the elements disclosed  
4 which is significant and the selection of which is well within  
5 the ordinary skill of those in the art to which this subject  
6 matter is useful and who wish to practice the invention.  
7 Accordingly the dimensions referred to herein are not intended  
8 to be limiting and are illustrative only.

9 While the disclosure of this invention has been shown and  
10 described in a preferred embodiment and in a best mode, it is  
11 recognized that departures therefrom may be within the spirit  
12 and scope of the invention, which is, therefore, not to be  
13 limited except by the claims and within the doctrine of  
14 equivalents.

15 Now that the invention has been described,